

REMARKS

Applicants and their representatives wish to extend their appreciation to Examiner Robinson for the very helpful discussions regarding this application and its related applications. During these discussions, Applicants expressed their intention of amending the claims in this application from recitation of "Therapeutic protein X" to "an antibody specific for Therapeutic protein X," wherein Therapeutic protein X is selected from at least one protein set forth in Table 1 of the specification. The Examiner then stated that a restriction would be required among the proteins in Table 1. Accordingly, in this response, Applicants have elected an "antibody or antibody fragment that specifically binds HER2." The Examiner is requested to make the restriction requirement of record. Applicants assert that the proteins set forth in Table 1 are independent and separately patentable, and that Applicants reserve the right to file divisional applications on the non-elected inventions.

In the instant application, claims 1-21 are under consideration. Claims 22-29 are withdrawn from consideration as being directed to non-elected inventions as restricted in the Restriction Requirement of August 4, 2003. Claims 1-12 have all been amended to change the recitation of "Therapeutic protein:X" to an "antibody or antibody fragment that specifically binds HER2." Support for these amendments can be found throughout the specification as filed, for example, at lines 25-34 on page 6, at line 10 on page 79 through line 30 on page 85, and in Table 1 on pages 41 and 42. Thus, the amended claims are fully supported by the specification. Additionally, subparts (e) and (i) of claim 1 have been cancelled and subparts (b), (c) and (d) have been amended to define the fragment with albumin activity as being a fragment or variant of "the amino acid

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sequence of SEQ ID NO:18.” Each of the issues raised in the Office Action of November 4, 2003, are addressed herein below.

Specification; Priority; Oath/Declaration

The Office has objected to the priority claims to provisional application nos. 60/229,358; 60/256,931; and 60/199,384, because the inventors on the provisional applications are different from the inventors on the instant application. Applicants have deleted the first paragraph of the specification to remove the priority claims to the provisional applications. Applicants have also requested a Corrected Filing Receipt that no longer makes reference to these provisional applications. It is believed that no new oath or declaration is necessary to disclaim the priority claims to these provisional applications.

Provisional Statutory Double Patenting

Claims 1-21 are provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-21 of copending Application Nos. 09/833,117; 09/833,111; 09/833,118; 09/832,501; and 09/832,041. Applicants have informed the Examiner that they will elect a single protein for “Therapeutic protein X” in each of the copending applications. Specifically, the following proteins have been elected in these copending applications:

<u>Application No.</u>	<u>Therapeutic protein X</u>
09/833,117	Interferon-beta (IFN-b)
09/833,111	Cerebus protein
09/833,118	Brain-derived neurotrophic factor (BDNF)
09/832,501	Interferon-alpha (IFN-a)
09/832,041	TIMP-1

The currently amended claims in the instant application are directed to an albumin fusion protein comprising an antibody or antibody fragment that specifically binds HER2, which is not being claimed in any of these above copending applications. Therefore, withdrawal of the rejections is respectfully requested.

Claim Rejections - 35 USC § 102

Claims 1-21 are rejected under 35 U.S.C. §102 (g) or (f) in view of copending application no. 09/832,501. The Office contends that the two applications are commonly assigned but have different inventive entities, that the two applications have the same language, scope, wording and subject matter, and that the assignee is therefore required to state which entity is the prior inventor of the conflicting subject matter. Applicants respectfully traverse.

A finding of anticipation under 35 U.S.C. §102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987). This standard precludes any finding of anticipation of the instant claims by copending application no. 09/832,501.

As discussed above, the amended claims now recite an "antibody or antibody fragment that specifically binds HER2." Copending application no. 09/832,501 does not claim the same "antibody or antibody fragment that specifically binds HER2" as in the instant application. Therefore, the two applications do not raise inventorship issues.

Withdrawal of the rejection is respectfully requested.

Claims 1-21 are also rejected under 35 U.S.C. §102 (e) as being anticipated over copending application no. 09/832,501. As explained above, copending application no.

09/832,501 does not disclose or claim the same "antibody or antibody fragment that specifically binds HER2" as in the instant application. Therefore, the copending application does not anticipate the instantly claimed invention. Withdrawal of the rejection is respectfully requested.

Claims 1-3, 5-10, 13, 14 and 17-21 are also rejected under 35 U.S.C. §102 (b) as being anticipated by WO 97/24445 ("Delta"), or its Korean equivalent, KR99076789.

The Office alleges that Delta discloses serum albumin fusion proteins comprising the sequence set forth in SEQ ID NO: 18 of the instant application and therefore anticipates the claimed invention. In particular, the Office alleges that Delta discloses a fusion of albumin and a growth hormone. The Office has interpreted "Therapeutic protein X" as encompassing any "polypeptide, antibody, peptide, fragments or variants thereof." See Office Action, page 9. However, the claims now recite an "antibody or antibody fragment that specifically binds HER2." Delta does not teach or suggest an albumin fusion protein comprising an antibody or antibody fragment specific for HER2. Thus, Delta does not anticipate the instant claims. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

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Respectfully submitted,

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